

427.035

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
KATY DRIEU
Serial No.: 555,906
Filed: June 2, 2000
For: USE OF...A MEDICAMENT

: K. Srivastava
:
: Group: 1651
:
:

600 Third Avenue
New York N.Y. 10016
April 8, 2002

BRIEF ON APPEAL

Asst. Commissioner for Patents
Washington, D.C. 20231

Sir:

REAL PARTY IN INTEREST

The real party in interest is Societe De Conseils De Recherches D'Applications Scientifiques (S.C.R.A.S.) by means of an assignment filed in the Patent Office with the application.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant, the Appellants' legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF THE CLAIMS

The claims in the application are claims 2 to 8 and 10 to 13, all other claims having been cancelled.



STATUS OF THE AMENDMENTS

The amendment filed February 21, 2002 was entered for purposes of appeal but did not put the application in condition for allowance.

SUMMARY OF THE INVENTION

The present invention is directed to a method of alleviating withdrawal symptoms of substance dependency or addiction in humans by administering to humans in need thereof a Ginkgo biloba extract in an amount sufficient to alleviate said withdrawal symptoms.

PRIOR ART

Hsia et al 5,976,548 November 1999
Kleijnen et al, Ginkgo biloba, Lancet, Vol. 340, pp. 1136-1139
Remington's Pharmaceutical Sciences et al, Philadelphia
College of Pharmacy and Science, pgs. 1287-1296.

The Hsia et al patent relates to nutritional supplements used to increase levels of high density lipoprotein (HDL) and calcium ions and to decrease levels of free radicals in glucose in human blood plasma comprising a combination of specific antioxidants, barley grass extract, specific multiple vitamins and minerals and

Ginkgo biloba extract which compositions are indicated as being useful for persons suffering from difficulties of concentration and memory, absent mindedness and confusion.

The Kleijnen et al reference relates to Ginkgo biloba extracts of varying compositions which are allegedly useful for peripheral vascular disease and the treatment of difficulties of concentration, lack of energy, tiredness, decreased physical performances and the like.

The Remington Pharmaceutical reference relates to pharmacological aspects of drug abuse and teaches that narcotics generally are drugs that diminish sensibility, relieve pain and induce lethargy, drowsiness or sleep. These are things such as cigarettes, alcohol, marijuana and volatile hydrocarbons as well as aerosol propellants.

THE ISSUES

All of the claims stand rejected under 35 USC 103 as being obvious over the Hsia et al patent and the Kleijnen et al reference taken in view of the Remington Pharmaceutical Sciences reference. The Examiner states that the Hsia et al patent teaches a nutritional supplement containing Ginkgo extract to enhance memory and improve mental activity and the like and the Kleijnen et al reference allegedly discloses pharmaceutical extracts from Ginkgo

leaves used to treat cerebral insufficiency including absent mindedness, anxiety depression, dizziness and headaches. The Remington reference is cited to show that withdrawal symptoms from alcohol abuse are manifested as headaches, nausea, insomnia, confusion, disorientation as well as similar treatment from cigarette smoking. The Examiner concedes that the two primary references do not teach the use of Ginkgo extracts to ease withdrawal symptoms of substance abuse or drug addiction and merely describes the symptoms of drug addiction, substance abuse and the like. The Examiner cites the Remington reference is cited as teaching repercussions of substance abuse and symptoms of substance abuse withdrawal and deems that in view of the primary references, Ginkgo extract and a dietary composition would help overcome similar symptoms that it would be useful for withdrawal symptoms of substance abuse.

GROUPING OF THE CLAIMS

All of the claims stand or fall together.

APPLICANT'S ARGUMENTS

Applicant respectfully requests the Board of Patent Appeals and Interferences to reverse the Examiner's rejection since one skilled in the art would not make the combination that the Examiner has made with the benefit of Applicant's teaching and there is no

suggestion in the prior art to combine the references as the Examiner has done. The Hsia et al patent relates to "nutritional supplements to the human diet to increase levels of high density lipoprotein and calcium ions and decrease levels of free radicals in glucose in human blood plasma". This is accomplished by a supposedly novel combination of specific antioxidants, barley grass extract, simple multiple vitamins and minerals and Ginkgo biloba extract. There is not one iota of a suggestion of alleviating withdrawal symptoms of substance dependency or addiction in a human. Therefore, there is absolutely no suggestion of Applicant's invention in this reference.

With respect to the Kleijnen et al reference, as noted above, it teaches pharmaceutical extracts from Ginkgo to treat cerebral insufficiencies that include absent mindedness and anxiety, depression and the like. Again, there is absolutely no teaching whatsoever or suggestion therein of treating withdrawal symptoms in humans.

As noted above, the Remington reference merely teaches various aspects of drug abuse with narcotics, alcohol, aerosol propellants, volatile hydrocarbons, cigarettes and marijuana. There is absolutely no teaching whatsoever of any method of treating withdrawal symptoms due to substance abuse by using Ginkgo biloba extracts which are not even mentioned in the reference. Therefore, there is no suggestion of combining the primary references with the

Remington reference to treat substance abuse with Ginkgo biloba extracts. There is no suggestion in the art to combine the references as the Examiner has done with the benefit of Applicant's teachings and there is no reasonable expectation of success. While there may certain symptoms of withdrawal that can be found in common with other diseases, there is actually no reliable medicine for easing withdrawal symptoms of alcohol or drug dependency while there are other drugs treating such symptoms. Applicant has shown in the application as filed that the Ginkgo extracts are useful for Applicant's purposes and there is no suggestion of combining the references as the Examiner has done.

One skilled in the art would not have guessed in an obvious manner that a drug used for decades and even centuries for completely different purposes such as memory improvement or venous insufficiency would be useful for easing withdrawal symptoms of narcotics and the like. It should be noted from the Remington reference that the conditions treated are not conditions created by narcotics and alcohol abuse and are not the same as those induced by a platelet activating factor (PAF) including a reduction in blood pressure, immediate allergic reaction, contraction of swollen muscles and the like. There is no suggestion whatsoever of Applicant's conditions being treated by the Remington reference such as moderate to intense psychopharmacologic effects such as those listed under the marijuana heading and psychic excitation, euphoria or high caused by amphetamines or intense

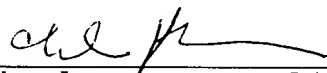
psychopharmacological dependency due to cocaine addiction. These are in no way related to the nutritional supplements taught by Hsia et al and are not in any way related to the conditions treated by the Park et al reference. Therefore, the combination of the prior art is completely improper and the rejection should be reversed.

CONCLUSION

It is believed that Applicant has complied with all the necessary requisites for the granting of Letters Patent and therefore, the Board of Patent Appeals and Interferences is respectfully requested to reverse the Examiner's rejections. Three copies of the appeal brief are being filed. Also enclosed is PTO Form-2038 authorizing the \$310.00 fee for filing the brief.

Respectfully submitted,
Bierman, Muserlian and Lucas

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CAM:ds
Enclosures



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APPENDIX

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Sir:

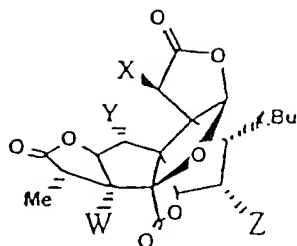
Claim 2. The method of claim 11, wherein the Ginkgo biloba extract is an extract comprising 20 to 30% of flavoneglycosides, 2.5 to 4.5% of ginkgolides A, B, C and J, 2 to 4% of bilobalide, less than 10% of proanthocyanodines and less than 10 ppm of alkylphenol compounds.

Claim 3. The method of claim 11 wherein the ginkgo biloba extract is an extract comprising 3.5 to 7% of ginkgolides A, B, C and J, 40 to 60% of flavoneglycosides and 5 to 7% of bilobalide.

Claim 4. The method of claim 11 characterized in that Ginkgo biloba extract contains at least 5% of ginkgolides.

Claim 5. The method of claim 11 characterized in that Ginkgo biloba extract contains at least 50% of ginkgolides.

Claim 6. The method of claim 11 wherein the extract contains a compound of the formula



(I)

in which W, X, Y and Z independently represent the H, OH, linear or branched alkoxy, a mono- or a disaccharide, or one of their derivatives or analogues, it being understood that at least one of W, X, Y or Z is a mono- or disaccharide.

Claim 7. The method of claim 6, wherein:

- either W is an OH or a mono- or disaccharide, Y is H and Z represents H;

- or W is OH or a mono- or disaccharide, Y is OH or a mono- or disaccharide and Z is OH;

- or W is OH or a mono- or disaccharide, Y is OH or a mono- or disaccharide and Z is OH or a mono- or disaccharide;

- or W is OH or a mono- or disaccharide, Y is H and Z is OH or a mono- or disaccharide;

- or W is OH or a mono- or disaccharide, and Z is OH or a mono- or disaccharide;

- or W is OH or a mono- or disaccharide, Y is a linear or branched alkoxy and Z is H;

it being understood that at least one of W, X, Y or Z is a mono- or disaccharide.

Claim 8. The method of claim 6 wherein:

- either W is OH or a mono- or disaccharide, Y is H and Z is H;

- or W is OH or a mono- or disaccharide, Y is OH or a mono- or disaccharide and Z is H;

- or W is OH or a mono- or disaccharide, Y is a linear or branched alkoxy radical and Z is H;

it being understood that at least one of W, X, Y or Z is OH or a mono- or disaccharide.

Claim 10. The method of claim 13 wherein the ginkgolide is ginkgolide-A or ginkgolide B.

Claim 11. A method of alleviating withdrawal symptoms of substance dependency or addiction in a human being comprising administering to said human being in need thereof a Ginkgo biloba extract in an amount sufficient to alleviate said withdrawal symptoms.

Claim 12. The method of claim 11 wherein the substance is selected from the group consisting of alcohol, tobacco, amphetamines and drugs and drugs inducing drug addiction.

Claim 13. The method of claim 11 wherein the extract is selected from the group consisting of a ginkgolide, a pharmaceutical salt thereof or a glycosylated, alkoxylated or acetylated ginkgolide.